

WHAT IS CLAIMED IS:

1. A taste-masking pharmaceutical composition comprising:
  - (a) a core region comprising an active pharmaceutical ingredient for which taste-masking is desired and at least one pharmaceutically acceptable excipient; and,
  - (b) a taste-masking film coating layer over the core, the taste-masking film coating layer comprising:
    - (i) a film-forming, water-insoluble polymer; and,
    - (ii) a pH dependent, water-insoluble polymer which dissolves at a pH level of about 5 or below.
2. The composition of claim 1, wherein the active pharmaceutical ingredient is desloratadine or it's pharmaceutically acceptable hydrates, salts or esters.
3. The composition of claim 1, wherein the film-forming, water-insoluble polymer is selected from the group consisting of ethylcellulose, polyvinyl acetate, cellulose acetate butyrate, methacrylic acid copolymers and mixtures thereof.
4. The composition of claim 1, wherein the pH dependent, water-insoluble polymer is a copolymer.
5. The composition of claim 3, wherein the copolymer is a polymethacrylic acid copolymer.
6. The composition of claim 1, wherein the film-forming, water-insoluble polymer is ethylcellulose and the pH dependent, water-insoluble polymer is a polymethacrylic acid copolymer.

7. The composition of claim 1, wherein the film-forming, water insoluble polymer is present in an amount from about 25 wt. % to about 75 wt. % and the pH dependent, water-insoluble polymer is present in an amount from about 30 wt. % to about 70 wt. %, based on the total weight of the coating layer.

8. The composition of claim 1, wherein the film forming, water insoluble polymer is present in an amount from about 40 wt. % to about 60 wt. % and the pH dependent, water-insoluble polymer is present in an amount from about 35 wt. % to about 55 wt. %, based on the total weight of the coating layer.

9. The composition of claim 1, wherein the pH dependent, water-insoluble polymer is present as discrete particles distributed homogeneously throughout the coating layer.

10. The composition of claim 1, wherein the active pharmaceutical ingredient is selected from the group consisting of antibiotics, analgesics, antihistamines, decongestants, antitussives, steroids, antibacterials, antiepileptics, , psychotropics, cardioitronics, antipyretics, antiulcer agents, anti-inflammatories, anti-allergic agents and mixtures thereof.

11. The composition of claim 1, wherein the amount of the active pharmaceutical ingredient in the core is from about 1 wt. % to about 40 wt. %, based on the total weight of the core.

12. The composition of claim 2, wherein the amount of the active pharmaceutical ingredient in the core is from about 1 wt. % to about 40 wt. %, based on the total weight of the core.

13. The composition of claim 1, wherein the amount of the active pharmaceutical ingredient in the core is from about 5 wt. % to about 35 wt. %, based on the total weight of the core.

14. The composition of claim 2, wherein the amount of the active pharmaceutical ingredient in the core is from about 5 wt. % to about 35 wt. %, based on the total weight of the core.

15. The composition of claim 1, wherein the amount of the active pharmaceutical ingredient in the core is from about 10 wt. % to about 30 wt. %, based on the total weight of the core.

16. The composition of claim 1, further comprising one or more pharmaceutical additives.

17. The composition of claim 14, wherein the one or more pharmaceutical additives is selected from the group consisting antioxidants, buffering agents, sweetening agents, binders, diluents, fillers, glidants, lubricating agents, disintegrants, and wetting agents.

18. The composition of claim 1, wherein the core is present in an amount of about 70 wt. % to about 95 wt. % and the coating is present in an amount of about 5 wt. % to about wt. 30 wt. %, based on the weight of the composition.

19. The composition of claim 1, wherein the core is present in an amount of about 80 wt. % to about 90 wt. % and the coating is present in an amount of about 10 wt. % to about 20 wt. %, based on the weight of the composition.

20. A process for preparing a taste-masking, film coated solid oral dosage composition comprising the step of coating a core comprising an active pharmaceutical ingredient having a taste for which masking is desired with a taste masking, film coating layer the taste-masking, film coating layer comprising (i) a film-forming, water-insoluble polymer; and, (ii) a pH dependent, water-insoluble polymer which dissolves at a pH level of about 5 or below.

21. The process of claim 20, wherein the active pharmaceutical ingredient is selected from the group consisting of antibiotics, analgesics, antihistamines, decongestants, antitussives, steroids, antibacterials, antiepileptics, , psychotropics, cardioitronics, antipyretics, antiulcer agents, anti-inflammatories, anti-allergic agents and mixtures thereof.

22. The process of claim 20, wherein the active pharmaceutical ingredient is desloratadine or it's pharmaceutically acceptable hydrates, salts or esters.

23. The process of claim 20, wherein the amount of the active pharmaceutical ingredient in the core is from about 1 wt. % to about 40 wt. %, based on the total weight of the core.

24. The process of claim 20, wherein the amount of the active pharmaceutical ingredient in the core is from about 5 wt. % to about 35 wt. %, based on the total weight of the core.

25. The process of claim 20, wherein the amount of the active pharmaceutical ingredient in the core is from about 10 wt. % to about 30 wt. %, based on the total weight of the core.

26. The process of claim 20, wherein the composition further comprises one or more pharmaceutical additives.

27. The process of claim 26, wherein the one or more pharmaceutical additives is selected from the group consisting of binders, disintegrants, wetting agents, diluents, lubricating agents, and fillers.

28. The process of claim 20 wherein the core is present in an amount of about 75 wt. % to about 95 wt. %, based on the weight of the composition.

29. The process of claim 20, wherein the core is present in an amount of about 80 wt. % to about 90 wt. %, based on the weight of the composition.

30. The process of claim 20, wherein the pH dependent, water-insoluble polymer is present as discrete particles distributed homogeneously throughout the coating layer.

31. The process of claim 20, wherein the film-forming, water-insoluble polymer is selected from the group consisting of ethylcellulose, polyvinyl acetate, cellulose acetate butyrate, copolymers of acrylic acid and mixtures thereof.

32. The process of claim 20, wherein the pH dependent, water-insoluble polymer is a copolymer.

33. The process of claim 32, wherein the copolymer is a polymethacrylic acid copolymer.

34. The process of claim 20, wherein the film-forming, water-insoluble polymer is ethylcellulose and the pH dependent, water-insoluble polymer is a polymethacrylic acid copolymer.

35. The process of claim 20, wherein the film-forming, water insoluble polymer is present in an amount from about 25 wt. % to about 75 wt. % and the pH dependent, water-insoluble polymer is present in an amount from about 30 wt. % to about 70 wt. %, based on the total weight of the coating layer.

36. The process of claim 20, wherein the film forming, water insoluble polymer is present in an amount from about 40 wt. % to about 60 wt. % and the pH dependent, water-insoluble polymer is present in an amount from about 35 wt. % to about 55 wt. %, based on the total weight of the coating layer.

37. The process of claim 34, wherein the pH dependent, water-insoluble polymer is present as discrete particles distributed homogeneously throughout the coating layer.